

Vutrisiran: Impact on Thyroid Function

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SUMMARY

- While TTR has a role in transporting thyroxine, no clinically relevant impact on thyroid function has been observed with vutrisiran.¹
 - Across vutrisiran clinical studies, including the phase 3 HELIOS-A and HELIOS-B studies, thyroid-related AEs were not identified as common AEs with vutrisiran treatment.²⁻⁴
 - Patients who had untreated hypothyroidism or hyperthyroidism were excluded from the phase 3 studies. Full physical examinations, including examinations of the throat and thyroid, were conducted at screening for both studies and during the treatment period for HELIOS-A.^{5,6}
- A cumulative post-marketing review of Alnylam Pharmaceuticals' global safety database did not identify any safety concerns with thyroid-related AEs and vutrisiran treatment.⁷

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CLINICAL DATA

Pooled Safety Analysis of HELIOS-A and HELIOS-B

A pooled safety analysis including data from 707 patients who received at least one dose of vutrisiran at any time during the HELIOS-A and HELIOS-B studies was conducted to evaluate the safety of vutrisiran in patients with ATTR who received treatment for up to 58 months.²

The HELIOS-A vutrisiran group consisted of 160 patients who received at least one dose of vutrisiran in the initial 18-month treatment period (n=122) or initially received patisiran in the treatment period and were re-randomized to receive vutrisiran during the RTE (n=38). The HELIOS-B vutrisiran group consisted of 547 patients who received at least one dose of vutrisiran during the double-blind treatment period (n=326) or initially received placebo during the double-blind period and transitioned to vutrisiran in the OLE (n=221).²

In the pooled safety analysis, thyroid-related AEs were not identified as common AEs from vutrisiran treatment. There were no safety concerns identified with thyroid-related AEs and vutrisiran treatment.²

GLOBAL SAFETY DATABASE

A cumulative post-marketing review of Alnylam Pharmaceuticals' global safety database did not identify any safety concerns involving thyroid function related to vutrisiran.⁷

ABBREVIATIONS

AE = adverse event; ATTR = transthyretin amyloidosis; OLE = open-label extension; RTE = randomized treatment extension; TTR = transthyretin.

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